Attachment 3 g

K020483

General Electric Medical Systems

FEB 2 8 2002

Advantage Workstation 4.1
510 (k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. **Identification of submitter:**
   Scott R. Evans
   Regulatory Affairs Specialist
   Telephone: 847-704-8878
   Fax: 847-704-8560
   Date Prepared: November 22nd, 2001

2. **Identification of Product:**

Device name	Advantage Workstation 4.1	Advantage Workstation 4.1
Classification name	PACS per 21CFR Section 892 2050	PACS per 21CFR Section 892 205
Manufacturer/ Distributor	General Electric Medical Systems 283, Rue de la Minière **78533 BUC Cedex France**	General Electric Medical Systems 800E. Business Center Drive Mount Prospect, IL 60056 USA

3. **Marketed Devices**

   Advantage Workstation is substantially equivalent to the devices listed below:

Model:	Advantage Windows Review Workstation
Manufacturer:	General Electric Medical Systems
510 (k):	K960613

4. **Device Description :**

   Advantage Workstation 4.1 is a review station, which allows easy selection, review, processing and filming of multi-modality DICOM images from a variety of diagnosis imaging systems. When interpreted by a trained physician, filmed images may be used as a basis for a diagnosis.

   The AW 4.1 is positioned to be the system of choice for all users of CT, MR, Vascular Xray, Cardiac Xray, Digital Xray, PET or even PET/CT systems, MG, NM, US, SR.

The GE Advantage Workstation 4.1 support the following Sun stations:

- Ultra 60
  - Dual processor 2x450MHz
  - Dual UltraSPARC-II* CPU
  - 1 GB RAM (expandable to 2GB)
  - Two 36 GB internal disc
  - 644 MB Internal CD writer (16x write/40x read).

- UltraSparc 80
  - QUAD Processor 4X450 MHz
  - Quad UltraSPARC-II* CPU
  - 2 GB RAM (expandable to 4 GB)
  - Two 36 GB internal disc internal disc
  - 644 MB Internal CD writer (12x write/40x read).

- Monitors specifications
  - SONY* Trinitron Color Monitor
  - SUN Flat Panel Monitor 18.1 LCD

Advantage Workstation 4.1 supports the following image networking:

  - Standard 10/100 Base-T Ethernet

The GE Advantage Workstation 4.1 is designed and produced by GE Medical Systems and has been previously submitted to PMN (K913770, K942120, K960613).

5. Indications for Use

The Advantage Windows Workstation 4.1 is a review station which allows easy selection, review, processing, filming and media interchange of multi-modality images from a variety of diagnosis imaging systems. When interpreted by a trained physician, filmed images may be used as an element for diagnosis.

6. Comparison with Predicate Device

The GE Advantage Workstation 4.1 is substantially equivalent to the following workstation:
Advantage Windows Review Workstation
Manufacturer: GE Medical Systems
510(k): K960613
Both of these workstations allow easy selection, review, processing, filming and media interchange of multi-modality images from a variety of diagnosis imaging systems.

7. Conclusions

Advantage Workstation 4.1 brings additional features in order to integrate seamlessly into the Radiology Department Workflow.

The entire potential new hazards has been studied and controlled by a Risk Management Plan:

- A hazard analysis/ Risk Management Summary
- A software development and validation process
- A software verification plan

Advantage Workstation 4.1 provides images comparable to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2002

General Electric Medical Systems
% Mr. Wolfram Gmelin
Technical Manager
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K020483
Trade/Device Name: Advantage Workstation 4.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: February 1, 2002
Received: February 13, 2002

Dear Mr. Gmelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1

STATEMENT OF INTENDED USE

510(k) Number (if known): K020483

Device name: Advantage Workstation 4.1

Indication For Use:

The Advantage Workstation 4.1 is a review station, which allows easy selection, review, processing, filming and media interchange of multi-modality images from a variety of diagnostic imaging systems. When interpreted by a trained physician, filmed images may be used as an element for diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020483

Prescription Use _____ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

PAGENOMFICHIER